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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,940	06/29/2001	Joseph S. Orlando	9151-16	9425

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EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 08/08/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/895,940

Applicant(s)

ORLANDO ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 35-41 is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 13, 15-22 and 27-30 is/are rejected.
- 7) ☒ Claim(s) 9-12, 14, 23-26 and 31-34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/29/01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Notice to Comply with Sequence Rules.

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Detailed Action

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Amino acid sequences present in Fig. 2 and 8 have not been included in the previously filed Sequence Listing. A new Sequence Listing is required.

Applicant must comply with the sequence rules, 37 CFR 1.821 - 1.825. Any reply to this Office Action that does not include compliance with the Sequence Rules will be considered non-responsive. Applicant is requested to return a copy of the attached Notice to Comply with the reply. However, the nature of the non-compliance has not precluded an examination of the application on the merits, the results of which are communicated below.

Claims 19-42 have been renumbered as 18-41 (as per the requirements of 37 CFR 1.126) because applicants inadvertently omitted claim 18 from the case.

Applicant's election without traverse of Group I, Claims 1-34 in Paper No. 13 is acknowledged.

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Claims 35-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-16, 18-20, 22 and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyer et al.

Applicants claim a packaging cell (293 cell) containing a plasmid comprising a sequence (DNA) encoding a mutant E4orf6 protein and capable of expressing (transiently) a mutant adenovirus E4orf6 protein, said protein containing at least one mutation in the region encoding amino acids 230-260 that renders said protein non-toxic to the host cell and disrupts the interaction between E4orf6 and E1B-55kDa protein. Applicants also claim a nucleic acid construct (plasmid) encoding the E4orf6 mutant.

Boyer et al. (J. Biol. Chem., May 2000, Vol. 275, No. 20, pp. 14969-14978, see whole article, particularly the Abstract; p. 14973, right column, first full paragraph; Fig. 3; paragraph bridging pp. 14973-14974) recites 293 cells (which are packaging cells for adenoviral vectors) containing a DNA plasmid encoding a mutant E4orf6 protein, said protein being mutated at amino acids 237-238 (C237/238S) that renders said protein non-toxic to the host cell and disrupts the interaction between E4orf6 and E1B-55kDa.

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Boyer et al. therefore teaches the claimed invention. It is noted that the C237/238S mutant is characterized by Boyer et al. as "inherently non-functional" (p. 14974, top left column) since the mutant performs none of the functions of the cytotoxic wild-type E4orf6. It must therefore be considered, absent evidence to the contrary, that the inherently nonfunctional mutant is non-toxic to cells.

Claims 1-8, 13, 15-22 and 27-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Orlando et al.

Applicants' invention is as described above. Additionally, in claim 17, applicants recite that the mutation occurs in amino acids 239-254 and in claim 21, that the packaging cell is stably transfected with the nucleic acid encoding the E4orf6 mutant. Also, in claims 1-8 and 13 applicants claim a method for packaging a recombinant viral vector comprising transfecting or infecting the aforementioned packaging cell with a recombinant adenoviral vector lacking a sequence encoding a functional E4orf6 protein, culturing the infected cells and harvesting the recombinant viruses produced.

Orlando et al. (cited by applicants, J. Virol., 1999, Vol. 73, No. 6, pp. 4600-4610, see whole article, particularly the Abstract; 4th, 5th and 8th paragraphs in the "Materials and Methods" section on p. 4601; Fig. 6; p. 4609, particularly left column, 2nd full paragraph and paragraph bridging the right and left columns) teach 293 cells containing a DNA plasmid encoding a mutant E4orf6, said protein being mutated at the 245 position (L245P) that renders the protein non-toxic to the cell (Orlando et al. discloses that expression of the L245P protein could be maintained indefinitely in 293 or

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HeLa cells (p. 4609, left column, and hence is non-toxic to the cells) and disrupts the interaction between E4orf6 and E1B 55-kDa. Orlando et al. also teach a method for packaging a recombinant adenoviral vector (dl1014) lacking a sequence encoding a functional E4orf6 protein, said method comprising infecting the aforementioned packaging cells with the recombinant adenovirus, culturing the cells so as to express the E4orf6 mutant and collecting the recombinant virus produced. Orlando et al. therefore teaches the claimed invention.

Miscellaneous:

In Claim 8, line 2, the term "a plasmids" should be "a plasmid".

Claims 9-12, 14, 23-26 and 31-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 9-12, 14, 23-26 and 31-34 are free of the prior art because the prior art does not teach or suggest the specific claimed mutations in the E4orf6 sequence or the method of packaging an adeno-associated viral vector (claim 14). The closest prior art to these claims is represented by Orlando et al. and Boyer et al. (both cited above).

No Claims are allowed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be submitted directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
August 3, 2003


DAVID GUZO
PRIMARY EXAMINER